**NOT FOR CITATION**

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

KEVIN DIMMICK,

Plaintiff,

v.

UNITED STATES OF AMERICA,

Defendant.

_____/

No. C 05-0971 PJH

**FINDINGS OF FACT AND CONCLUSIONS OF LAW**

This Federal Tort Claims Act ("FTCA") case has a lengthy procedural history. Over the course of the two and one-half years that this case, or a related case, has been pending before the court, all but one of plaintiff Kevin Dimmick's ("Dimmick") claims have been dismissed. On October 16, 17, and 19, 2006, the matter came before the court for a three-day bench trial as to Dimmick's sole surviving claim. Following the bench trial, the parties submitted proposed findings of fact and conclusions of law, supplemented by citations to the evidence presented at trial. Based on the evidence presented at trial, and pursuant to Rule 52(a) of the Federal Rules of Civil Procedure, the court makes the following findings of fact and conclusions of law.

## PROCEDURAL BACKGROUND

Dimmick is a disabled veteran with HIV/AIDS who sought treatment at the Veterans' Administration Medical Center of San Francisco ("SFVAMC"). In the cases before this court, Dimmick claimed that the SFVAMC and other organizations affiliated with the

SFVAMC, including the Regents of the University of California ("the Regents") and Northern California Institute for Research and Education ("NCIRE"), conspired to deny him medical care and forced him to take medications which had previously caused him negative side effects. Dimmick also claimed that SFVAMC doctors failed to obtain proper informed consent from him, and defamed him to third parties.

Dimmick sued the Regents and private companies NCIRE, Boehringer-Ingleheim ("BI"), and Abbott Laboratories ("Abbott") in case number, C 04-4965 PJH, and the federal government in case number, C 05-0971 PJH. These two cases have had a complex procedural history. Dimmick originally filed one case in the San Francisco Superior Court against all of the parties and various federal employees of the SFVAMC. The government removed the case entitled *Dimmick v. Volberding*, C 04-1480 PJH, to federal court. This court then dismissed the federal defendants in case number C 04-1480 PJH because Dimmick had not exhausted his administrative remedies against them, and remanded the remaining claims against the non-federal defendants to state court.

Dimmick then filed a second amended complaint in state court, which did not explicitly name any federal employees but which contained claims against private parties based on the actions of VA employees. The government then removed the case a second time, at which point it became *Dimmick v. NCIRE*, C 04-4965 PJH. Dimmick moved to remand the case, but at the hearing on the motion, he withdrew his motion to remand and agreed to proceed on his claims in federal court.

Dimmick then filed a third amended complaint ("3AC") in C 04-4965 PJH and, after exhausting administrative remedies as required by the FTCA, filed a third lawsuit, this time against the government, *Dimmick v. U.S.*, C 05-0971 PJH. The two cases were subsequently related but not consolidated on this court's docket.

All defendants moved to dismiss the 3AC in *Dimmick v. NCIRE*, C 04-4965 PJH. The court granted the motion to dismiss but also granted leave to amend. Additionally, at Dimmick's request, the court granted Dimmick leave to amend the complaint in *Dimmick v.*

*US*, C 05-0971 PJH.

Dimmick then filed a fourth amended complaint ("4AC") in case number 04-4965 PJH and a first amended complaint ("1AC") in case number 05-0971 PJH in June 2005. After the filing of the 4AC, BI and Abbott settled their claims with Dimmick and were dismissed from *Dimmick v. NCIRE*, C 04-4965 PJH.

In September 2005, this court granted NCIRE's motion to dismiss the claims against it in 04-4965 PJH, and judgment was entered as to NCIRE on October 19, 2005. The court, however, denied the Regents' motion to dismiss. Accordingly, the only claims that remained in 04-4965 PJH after this court's September 2005 order were the seventh and eighth claims for breach of contract and declaratory judgment against the Regents. The Regents subsequently filed an answer to the 4AC in 04-4965 PJH on October 19, 2005.

In the September 2005 order, the court also denied the government's motion to dismiss the single negligence claim asserted under the FTCA in *Dimmick v. U.S.*, C 05-0971 PJH. The court, however, granted the government's motion for a more definite statement ("MDS").

After Dimmick filed the MDS, the government moved for judgment on the pleadings in C 05-0971 PJH. Subsequently, on February 3, 2006, the court granted in part the government's motion for judgment on the pleadings, leaving only one claim, in which Dimmick asserted that the government was negligent in failing to obtain his informed consent prior to prescribing HIV drugs. Thereafter, on April 18, 2006, Dimmick and the Regents stipulated to dismiss 04-4965 PJH with prejudice. Thus, the remaining claim in 05-0971 PJH was all that was left of Dimmick's cases.

On March 31, 2006, the government filed a motion for summary judgment as to the remaining claim. The court heard argument on May 10, 2006, and denied the government's motion on May 12, 2006.

As noted, the court has reviewed six different complaints during the pendency of Dimmick's three cases against the VA and others. His claims changed to varying degrees

with each amendment, although he has continued to argue theories that the court has rejected in earlier orders. With regard to informed consent, the only issue remaining to be tried, the court has already found that because Dimmick was not a subject of human experimentation, the VA doctors were not required to provide the kind of information that state and federal law requires they give to research subjects. The court also found that the VA doctors were required to provide sufficient information, such as that required by the provision of routine medical care, to enable Dimmick to provide "garden variety" consent. Additionally, it was unclear whether there was some requirement for more detailed information than that required for routine medical care for someone like Dimmick who, while not a research subject, may have been prescribed drugs in anticipation of his potential participation in research. Thus trial would be necessary to determine exactly what Dimmick's status was, what precise information he was provided, and whether whatever information he was provided was sufficient to inform his consent to the treatment he received.

Lastly, Dimmick's position on whether the VA doctors were required to obtain his written consent rather than his oral consent, has not been entirely consistent. The government attempted to clarify and narrow plaintiff's position at both the hearing on its motion for summary judgment and in its motion in limine, to one involving only whether the VA had a duty to obtain Dimmick's written consent. However, the court ordered that the trial would be on the issue of whether Dimmick gave informed consent to his treatment. The government argued that no written consent was required and that Dimmick gave his oral consent which was sufficiently informed. Dimmick seemed to argue that his written consent was required and that he did not consent in writing, and that even if only his verbal consent was required, it was no sufficiently informed.

## FINDINGS OF FACT

The court first sets forth a brief description of the parties and medical personnel who testified at trial.

**A. Parties/Witnesses**

*Kevin Dimmick*

Plaintiff Kevin Dimmick is a veteran who was diagnosed as HIV positive in 1991. Since then, he has been diagnosed with AIDS. In addition to drug-resistant HIV/AIDS, Dimmick has been treated for other medical conditions including attention deficit hyperactivity disorder ("ADHD"), asthma, and various opportunistic infections. Dimmick takes an active role in the treatment of his HIV, and "is always bringing up alternatives," in an approach that his treating physician characterized as "challenging." His treating physician also agrees, though, that Dimmick often has "good general insights into . . . many aspects of [his] HIV infection and AIDS."

*Dr. Jon Green*

Dr. Jon Green, Dimmick's treating physician, and an associate chief of staff and chief of infectious diseases, at the Veterans Affairs ("VA") Medical Center in Martinez, California, has been treating Dimmick for approximately ten years.

*Dr. Julie Higashi*

Dr. Higashi was one of the SFVAMC doctors who examined Dimmick on November 7, 2002. At the time of the visit, Dr. Higashi was a University of California at San Francisco ("UCSF") fellow in infectious diseases. She is currently the attending physician in the SFVAMC's infectious disease ("ID") clinic, and an assistant professor of medicine at UCSF. Dr. Higashi is board-certified in internal medicine, with a sub-specialty in infectious diseases. The court qualified her as an expert in infectious diseases.

*Dr. Harry Lampiris*

Dr. Lampiris was the attending physician supervising Dr. Higashi on November 7, 2002. He also met with Dimmick that day. Dr. Lampiris has been the assistant chief of the ID clinic at SFVAMC since 1993. He is board-certified in internal medicine, with a subspecialty in infectious diseases. He is also a clinical professor of medicine at UCSF. The court qualified Dr. Lampiris as an expert in infectious diseases with a specialty in

HIV/AIDS.

Dr. Lampiris also serves as the associate chief of staff for clinical research, and his responsibilities include supervising the SFVAMC research clinic, which is separate from the ID clinic. Since 1993, Dr. Lampiris has been a principal or sub-investigator for approximately 45 clinical drug trials related to the treatment of HIV and other infectious diseases.

Dr. Lampiris has also served as a consultant for Abbott Laboratories, the manufacturer of kaletra, an HIV medication that he prescribed to Dimmick on November 7, 2002. The VA policy regarding conflict of interest allows physicians to serve as expert consultants and function as scientists "outside their tour of duty" at the VA.

There is clearly a difference between a consultant role and a research role. Although the distinction was not fully developed at trial, a consultancy role appears to be akin to that of a scientific advisor, rather than a researcher. *See* Tr. Oct. 17, 2006, at 28. A physician may not serve as a consultant with respect to drugs that she or he is researching. *See id.* In other words, VA policy permits a doctor, like Dr. Lampiris, to consult for pharmaceutical companies as long as they are not conducting research for that company at the same time. Dr. Lampiris received compensation from Abbott in his capacity as a consultant for them.

*Dr. Mai Vu*

Dr. Vu is the HIV clinical pharmacist at the SFVAMC's ID clinic. She is also an associate professor in the department of pharmacy at UCSF. She also saw Dimmick on November 7, 2002. The court qualified Dr. Vu as an expert in the practice of pharmacology.

*Dr. Peter Jensen*

Dr. Jensen is the director of SFVAMC's ID clinic and the HIV program. He did not see Dimmick on November 7, 2002, but instead saw Dimmick for a follow-up visit on February 6, 2003. The court qualified Dr. Jensen as an expert in infectious diseases.

*Dr. Beckley*

Dr. Beckley is the director of the neuromuscular clinic at the Martinez VA medical center. He is a neurologist with a subspecialty in EMG electrical studies, and the court qualified him as an expert in that field. Dr. Beckley saw Dimmick on May 25, 2003, and then on March 4, 2004, related to Dimmick's complaints regarding neuropathy.

**B. HIV/AIDS Generally**

HIV is a retrovirus that enters the nucleus and DNA of CD4 cells, also known as T-cells. CD4 cells fight infection and are important to the body's immune system. A normal CD4 count is between 500 -1500. HIV, however, infects and destroys CD4 cells. Once HIV enters a CD4 cell, new HIV particles are assembled in the CD4 cell, and subsequently leave the infected cell, infecting and destroying additional CD4 cells.

Opportunistic infections are complications of HIV that can cause death and usually occur when a patient's CD4 count is less than 200. The CD4 cells are a measurement of the immune function, and a very low CD4 count is associated with a high risk of serious infections and cancers.

The viral load is the measure of the amount of HIV in the blood, and is an important indicator of HIV progression. Generally, the higher the viral load, the greater the risk to the patient. If a patient's viral load may be significantly reduced, the chance that the patient will experience opportunistic infections or other adverse AIDS-related malignancies is also greatly reduced.

Successful treatment of HIV/AIDS usually requires a lifelong therapy, in which a "drug cocktail" comprising three to six medications is administered in combination. A significant, if not driving purpose of the drug therapy is to lower the HIV in the blood, in other words, the viral load, leading to an increase in the CD4 count, and restoration of the immune system.

The medications that comprise a drug regimen are generally chosen among three (sometimes four) available classes of antiretroviral agents ("AVR"). Among the classes of

medications are: (1) non-nucleoside reverse transcriptase inhibitors ("NNRTI"); (2) nucleoside/nucleotide analogues; and (3) protease inhibitors ("PI"). When a patient has advanced HIV, certain mutations can occur that may decrease the effectiveness of different drugs, and are considered by physicians in determining the appropriate drug regimen. These mutations play a role in the resistance of a patient's HIV to particular medications. Physicians rely in part on the results of blood tests and genotype tests to determine a patient's resistance and which drugs will be the most effective.

The HIV drug regimens are often complex, and all pose a risk of a variety of side effects. Peripheral or sensory neuropathy is a common side effect of some HIV medications. There was no evidence explaining whether there is any distinction between sensory and peripheral neuropathy. Based on the witnesses' usage of the terms, it appears that they are interchangeable. While Dimmick claims to have suffered from neuropathy, he failed to elicit a technical definition of neuropathy from the doctors who testified in this case. However, based on the testimony, the court is able to infer that neuropathy is a loss of sensation, which often occurs in one's extremities. Additionally, a leading medical dictionary defines neuropathy as "an abnormal and usually degenerative state of the nervous system or nerves." Merriam-Webster Medical Dictionary, http://dictionary.reference.com/medical/ (last visited Dec. 15, 2006).

Peripheral neuropathy can be caused by the HIV virus itself ("HIV neuropathy") as well as by drugs ("drug-induced neuropathy"). The two are clinically indistinguishable. Generally, if the neuropathy resolves after reducing or discontinuing a drug known to be associated with a neuropathic side effect, then it will most likely be diagnosed as drug-induced neuropathy. However, if the neuropathy persists following termination of the drug, then it may be regarded as HIV neuropathy.

Approximately 30-50% of Dr. Lampiris' HIV patients have reported subjective complaints of peripheral neuropathy. Among the drugs that are known to cause neuropathy are ddI and D4T. The combination of ddI and D4T in a drug therapy is eight

times more likely to cause neuropathy than ddI alone.

**C. Dimmick's Medical History Prior to November 7, 2002**

At the time that Dr. Green began treating Dimmick in the 1990's, there were fewer treatment options than there are today. Both Dimmick and Dr. Green watched in a "state of shock," as Dimmick's CD4 count declined. However, soon after multi-drug therapy was developed, Dimmick was one of Dr. Green's first patients started on HIV drugs in the 1990's.

Since Dr. Green began treating Dimmick, his HIV has become increasingly drug-resistant. Between 1997 and September 2002, Dimmick was on a number of different AVR regimens comprised of a variety of different drugs, including ddI, ritonavir, and tenofovir, all at issue in this case. Most of these drugs were FDA-approved, and were prescribed by Dr. Green without obtaining Dimmick's written consent. [1]

Additionally, beginning in 1997, Dimmick was on a combination of drugs including stavudine (also known as D4T), which he discontinued in 2000 due to resulting neuropathy. Dimmick described the neuropathy that he experienced as a feeling that his socks were bunching up under his feet. It was a very uncomfortable experience for Dimmick.

Subsequently, in May 2001, Dimmick tried a drug regimen that included ritonavir and tenofovir. Soon after, Dimmick developed depression, and contrary to Dr. Green's recommendation that he continue with the ritonavir, discontinued the regimen in October 2001.

In January 2002, Dimmick's CD4 count was dangerously low - only 19. As a result,

---

[1]Dimmick took tenofovir from May - October 2001. *See* Def. Exh. A7. However, tenofovir did not receive FDA-approval until October 26, 2001. *See* U.S. Drug and Food Administration, Drugs Used in the Treatment of Aids, http://www.fda.gov/oashi/aids/virals.html (last visited December 7, 2006). This document was submitted as Def. Exh. A39, but was not admitted at trial. However, the information contained on the agency's chart regarding dates of approval of HIV medications may be judicially noticed.

It is unclear from the record how Dimmick obtained the non-FDA approved HIV medication, but it is not disputed that he was taking tenofovir prior to its approval by the FDA. There was no evidence as to whether Dimmick's written consent was obtained before it was prescribed.

in February 2002, Dimmick again tried a three-drug combination including both ddI and D4T, the drug that had previously resulted in neuropathy in 2000. In April 2002, Dimmick again developed neuropathy, and discontinued that regimen. Thereafter, Dimmick was placed on another drug regimen, on which he remained until September 30, 2002, due to his recurring or continuing complaints of neuropathy.

At the end of September 2002, Dimmick went on a medication "hold" or a "drug holiday." His viral load at this time was very high - approximately 428,000. Def. Exh. A5. His CD4 count was very low at 94. Pl. Exh. 3.

Around the same time, in the fall of 2002, Dr. Green referred Dimmick to the ID clinic at the SFVAMC for a number of reasons, including the fact that Dr. Green thought the SFVAMC was better-staffed and had better HIV resources than the VA's Martinez facility where Dr. Green worked. Dr. Green also referred Dimmick to SFVAMC to determine whether any experimental drugs or clinical trials were available.

Dr. Green considered SFVAMC to be one the best and foremost HIV treatment centers. At any given time, SFVAMC's ID clinic treats 600 HIV patients, approximately one-half of whom have drug-resistant HIV. There is also a research clinic at the SFVAMC, which is separate from the ID clinic. The research clinic constitutes a more controlled environment than that of the ID clinic. Dimmick, however, was never seen at the research clinic.

Dr. Green made the referral by calling Dr. Mai Vu, the HIV clinical pharmacist at the clinic. He did not talk to either of the SFVAMC doctors who later saw Dimmick, Drs. Lampiris and Higashi.

**D. November 7, 2002 SFVAMC Visit**

On October 8, 2002, approximately one month prior to Dimmick's November 7, 2002 visit to SFVAMC, Dr. Phil Drum, a pharmacist at the Martinez VA, faxed Dr. Vu certain documents regarding Dimmick's HIV treatment. Def. Exh. A-7. The documents included a chronological record of the drug regimens Dimmick had tried, a genotype study, and email

correspondence between Dr. Green and Dr. Mark Holodniy, another HIV specialist, regarding the results of one of Dimmick's genotype studies.

The faxed documents indicated that Dimmick had already tried multiple regimens and was showing signs of extensive resistance to all three classes of HIV medications. They also showed that Dimmick had multiple PI (protease inhibitors) and RT (reverse transcriptase inhibitor) mutations. The documents reflected that Dimmick had a "pretty high level resistance to almost everything," but that kaletra (which contains ritonavir) and ddI would still have some "activity" against his virus. An email message suggested that Dr. Holodniy believed that atazanavir and tenofovir, two drugs that had not yet been approved by the FDA, might be useful in treating Dimmick's HIV.

On November 7, 2002, Dimmick was seen first by Dr. Higashi, who reviewed the documents faxed by Dr. Drum immediately prior to conducting Dimmick's physical examination. Dr. Higashi did not have any additional information at the time she treated Dimmick. While Dr. Higashi had one genotype report for Dimmick that was included in the information faxed by Dr. Drum, *see* Govt. Exh. A-7, she did not have any "Trugene" genotype reports, which Dr. Lampiris also testified that he did not have at the time of Dimmick's visit (discussed below).

Dr. Higashi saw Dimmick for the purpose of evaluating him and treating his HIV. Dimmick was in bad shape that day. He had a very high viral load, a low CD4 count, and absolutely needed treatment. According to Dr. Higashi, Dimmick suffered from very advanced drug-resistant HIV. While she was examining Dimmick, Dr. Higashi discussed with him his reasons for coming to the SFVAMC, HIV medications that he had taken in the past, resulting symptoms and side effects, and whether he needed additional medications for opportunistic infections.

Dr. Higashi understood from Dimmick that he hoped to participate in a clinical drug trial in the future, but that he also understood that his HIV was very severe. While Dr. Higashi believed the purpose of the visit was to provide Dimmick HIV treatment, she was

"sensitive" to Dimmick's desire to participate in a future clinical drug trial.

After conducting the initial physical examination and consultation with Dimmick, Dr. Higashi consulted Dr. Lampiris to devise a treatment plan. Subsequently, Drs. Higashi and Lampiris saw Dimmick together.

Dimmick asked Dr. Lampiris for access to atazanavir, a PI not yet approved by the FDA. Based on Dr. Lampiris' experience and expertise, he believed atazanavir was not effective in suppressing the HIV virus in patients, such as Dimmick, with an accumulated number of protease mutations. By contrast, he believed Dimmick's HIV would likely be more responsive to other PI's – namely, kaletra (which contains ritonavir), indinavir, and amprenavir. Dr. Lampiris explained to Dimmick that his virus was too resistant for him to derive any benefit from atazanavir. Additionally, as of November 2002, atazanavir was not yet available at the SFVAMC.

Drs. Higashi and Lampiris also discussed with Dimmick the drug, T20, a new class of HIV medication that was not yet FDA-approved. However, T20 required refrigeration, and Dimmick rejected medications requiring refrigeration.

Given Dimmick's low CD4 count and high viral load, as of November 7, 2002, Dimmick's HIV required rapid initiation of an HIV treatment regimen which would be active against and suppress Dimmick's HIV disease. Even if Dimmick's viral load could not be reduced to undetectable levels, HIV drug therapy was nevertheless essential for reducing Dimmick's risk of disease progression or death.

Dr. Lampiris therefore recommended to Dimmick a regimen of ddI, kaletra, indinavir, and amprenavir. Each of these drugs was FDA-approved for the treatment of HIV/AIDS, and was commercially available. It was Dr. Lampiris' opinion that these drugs were still active against Dimmick's HIV and would provide the optimal effectiveness against his disease. Dr. Lampiris prescribed the drug regimen for the purpose of stabilizing Dimmick's HIV.

Dr. Lampiris determined the propriety of the regimen based on the medical

information available to him and on his expertise and experience. He determined that kaletra was "fully active" as a protease inhibitor given Dimmick's resistance mutations. He also determined that the protease inhibitor, indinavir, was appropriate given Dimmick's mutations.

As for ddI, Dr. Lampiris concluded that it was the most effective in its category of medications. He considered tenofovir, but concluded that it would have "minimal activity" given Dimmick's mutations. He did not discuss tenofovir with Dimmick. Dr. Lampiris also considered atazanivir, as requested by Dimmick. As noted, in addition to its unavailability, Dr. Lampiris also opined that atazanavir would be less effective than ddI, and that there would be minimal response given Dimmick's mutations.

At the time that Dr. Lampiris prescribed the drug regimen, he knew from Dimmick's medical records and from his conversation with Dimmick that Dimmick had previously experienced side effects from both ddI and ritonavir. As for ddI, Dr. Lampiris noted that previously, Dimmick had experienced neuropathy after taking a combination of ddI and D4T. Dr. Lampiris explained to Dimmick that ddI alone was far less likely to cause neuropathy than ddI and D4T taken together.

In the presence of Dimmick's specific mutations, Dr. Lampiris expected ddI to be very active against Dimmick's high viral load. Weighing the expected benefits of ddI in suppressing Dimmick's viral load against the reduced risk that Dimmick would experience neuropathy from ddI alone, Dr. Lampiris told Dimmick that he felt, in his clinical judgment, that it would be worth Dimmick trying ddI again. Dr. Lampiris also told Dimmick to watch out for signs of neuropathy, and that if neuropathy occurred, they could either decrease the dosage or discontinue the drug.

As for the ritonavir, Dimmick expressed concerns regarding the depression that he believed ritonavir had caused him in the past. Dr. Lampiris told Dimmick that depression was an extremely rare reaction to ritonavir. Dr. Lampiris recommended that it was worth "rechallenging" Dimmick on ritonavir. Dr. Lampiris' recommendation was based in part on

the drug's important role in the treatment of advanced HIV patients. Low dosage ritonavir, such as that proposed by Dr. Lampiris, functions as a "booster" for other PI's, thereby increasing the effectiveness of those PI's. In Dr. Lampiris' opinion, Dimmick had relatively few viable options available to him. Moreover, any resulting depression could be treated.

Like with Dr. Higashi, Dimmick also asked Dr. Lampiris about available drug studies at SFVAMC. Dimmick was highly focused on the possibility of getting into a clinical drug trial. Indeed that possibility was one of the reasons for the referral to SFVAMC in the first place in addition to his need to resume immediate treatment and to end his "drug holiday." However, there were no open or pending drug studies or clinical trials available at that time. Dr. Lampiris advised Dimmick that there were no open or pending drug studies as well as the requirement that drug study participants be on a stable AVR for at least two months prior to enrollment in any study. At the time of Dimmick's appointment, a clinical trial of the drug tipranavir was scheduled for spring 2003; however, the study was awaiting final approval and enrollment was not yet open. Dr. Lampiris told Dimmick that a study of tipranavir was planned, but did not promise Dimmick that he would be in that study. *See* Tr. Oct. 19, 2006, at 39.

Drs. Lampiris and Higashi did not recommend the particular drug regimen that day as part of any ongoing drug study or to prepare Dimmick for participation in any particular study, including the tipranavir study. As noted above, the doctors recommended the particular regimen to stabilize Dimmick's HIV, and because, in their professional judgment, they believed the regimen was the most effective regimen available. In fact, if Dimmick had not agreed to the recommended drug regimen, Drs. Lampiris and Higashi would have recommended another, though less optimal, drug regimen since there would have been no reason to prescribe a regimen that Dimmick refused to follow.

Dr. Lampiris did not and could not promise Dimmick that he would be enrolled in the upcoming tipranavir study (Spring 2003) or that Dimmick would receive investigational drugs. Nor did Dr. Lampiris advise Dimmick that in order to be eligible for upcoming drug

trials, that he had to be on the *specific* drug regimen recommended. Instead, as noted above, Dr. Lampiris advised Dimmick simply that potential applicants were required to be on *a* stable regimen.

The tipranavir study's two-month requirement of a stable regimen for eligibility was not unique to that particular study, but is required for any HIV/AIDS drug trial. It is a standard requirement because the purpose of such studies is to evaluate the efficacy of the new drug being tested. It was Dr. Lampiris' goal to treat Dimmick's HIV, and if the regimen proved successful, Dimmick could apply for any future drug studies that he might qualify for.

After asking several questions, Dimmick agreed to take the drug regimen recommended by Drs. Lampiris and Higashi with full knowledge that neuropathy was a potential side effect of ddI, and that depression could reoccur with the ritonavir. His oral consent was noted in a progress note prepared by Dr. Higashi. Pl. Exh. 3.

After seeing Drs. Higashi and Lampiris, Dimmick also briefly saw Dr. Vu, the SFVAMC clinical pharmacist. Dr. Vu saw Dimmick for the purpose of counseling him regarding the side effects of each of the drugs that had been prescribed. Dimmick told Dr. Vu that although he was very knowledgeable about the drugs and their side effects, he would "let her do her job." As part of the counseling, Dr. Vu gave Dimmick written information sheets that described in part the potential side effects of the drugs prescribed. She also gave Dimmick her name and office number, and advised him to call her or the SFVAMC clinic if he had problems.

**E. Post- November 7, 2002 SFVAMC Visit**

Approximately one or two weeks after starting the drug regimen prescribed on November 7, 2002, Dimmick began experiencing sensory neuropathy. He called both the SFVAMC and Martinez VA clinics. Dr. Vu returned Dimmick's call on November 25, 2002. At that point, Dimmick had already stopped taking the ddI. Meanwhile, on November 26, 2002, Dimmick had his blood drawn. A blood test that day revealed that his viral load had

dropped from the September 30, 2002 load of 428,400 to 41,400, suggesting that the November 7, 2002 regimen had indeed been active against Dimmick's HIV disease.

In January 2003, Dimmick called the Office of the Director of the SFVAMC, and complained about the care he received on November 7, 2002.[2] The complaint was directed to Dr. Lampiris. This was the first time that Dr. Lampiris learned that Dimmick had a complaint regarding his treatment. When Dr. Lampiris subsequently called Dimmick, Dimmick hung up on him.

On February 6, 2003, Dimmick was seen by the director of the SFVAMC ID clinic and HIV program, Dr. Jensen. Dr. Jensen agreed to see Dimmick after Dimmick refused to see either Drs. Higashi or Lampiris again.[3]

At the time Dr. Jensen saw Dimmick, he was aware that the regimen devised by Drs. Lampiris and Higashi was optimal in treating Dimmick's HIV, but that Dimmick could not tolerate the side effects - specifically, the neuropathy. However, Dr. Jensen knew that it was essential that Dimmick be on a drug regimen given the state of his HIV. Therefore, Dr. Jensen selected a new regimen based on Dimmick's own recommendation of HIV drugs that he believed he could tolerate. The regimen included zidovudine (AZT), lamivudine (3TC), delavirdine (DLV) and nefinavir (NFV).

When prescribing this regimen, Dr. Jensen knew that it was not optimal and would not likely result in full viral suppression. However, to ensure that Dimmick was on some sort of drug therapy, he prescribed it because the treatment – even if not the "gold standard" – was better than no treatment.

During the office visit, Dimmick also inquired of Dr. Jensen regarding upcoming drug studies. Dr. Jensen knew that there were upcoming studies, but none were open for

---

[2]There is no record evidence other than Dr. Lampiris' testimony regarding the specifics of Dimmick's complaint, and other than the fact that Dimmick was very angry regarding the care he received, the nature of the complaint is not clear. *See* Tr. Oct. 19, 2006, at 40-41.

[3]Dr. Jensen did not testify regarding the details of any conversations that he had with Dimmick concerning Dimmick's dissatisfaction with Drs. Lampiris' and Higashi's care and treatment. *See, e.g.*, Tr. Oct. 19, 2006, at 41-54.

enrollment at the time. He advised Dimmick that he would notify him if a study became available, but that he could make no promises that Dimmick would be able to participate in any of the studies.

Dr. Jensen prescribed the drug therapy that he did not for the purpose of enrolling Dimmick in a study or ensuring Dimmick's eligibility, but instead to stabilize Dimmick's HIV and attempt to lower his viral load.

On March 31, 2003, Dr. Lampiris sent Dimmick's treating physician, Dr. Green, a letter announcing the upcoming availability of the tipranavir study. The eligibility criteria for the tipranavir study included in part: "[a]t least 3 consecutive months experience taking ARV's from each of the classes of NRTIs, NNRTs, and PIs at some point in the treatment history, [w]ith at least 2 PI-based regimens, one of which must be the current regimen, and [c]urrent PI-based AVR medication regimen for at least 3 months prior to randomization." Def. Exh. A31. There were no limitations on which drugs could be used to in the AVR regimen.

Dimmick, however, did not apply for the tipranavir study, and was, therefore, never enrolled in the study.

As noted, following his November 7, 2002 visit to the SFVAMC, Dimmick complained of neuropathy. A few months after Dimmick saw Dr. Jensen at the SFVAMC in February 2003, he first saw Dr. Beckley at the Martinez VA on May 28, 2003. Dr. Beckley conducted a neurological examination, which revealed abnormalities in Dimmick's sensory nerves in his feet, a reduction in the size of the responses of the nerves, and somewhat delayed responses. According to Dr. Beckley, the neuropathy could have been induced by the ddI Dimmick was prescribed on November 7, 2002, or induced by the HIV itself. Based on Dimmick's subjective complaints and the temporal proximity to his ingestion of ddI, Dr. Beckley's initial impression was that the neuropathy was drug-induced.

Dr. Beckley then saw Dimmick for a follow-up visit on March 4, 2004, and again conducted a neurological examination. Dr. Beckley concluded that the result of that exam

reflected "marked improvement," and that Dimmick was back to normal.

To the extent that Dimmick continues to suffer from neuropathy post- March 2004, Dr. Beckley opined that the neuropathy is HIV, rather than drug-induced. He explained that drug-induced neuropathy is both dose- and time-sensitive, and that if it stabilizes or resolves after discontinuation of the drug, then the neuropathy would be regarded as drug-induced. However, if the neuropathy worsens following discontinuation of the drug, then it is generally regarded as HIV-induced.

**F. FDA Guidelines and Investigation**

In addition to complaining to the SFVAMC regarding his November 7, 2002 appointment with Dr. Lampiris, Dimmick also complained to the Federal Drug Administration ("FDA") and Boehringer Ingelheim ("BI"), the manufacturer of tipranavir.

Dimmick complained to the FDA that Dr. Lampiris had prescribed certain drugs in order to enroll him in a drug study without first obtaining his informed consent. The FDA subsequently conducted an investigation of Dimmick's complaint against Dr. Lampiris. However, because FDA guidelines require that informed consent be obtained prior to the performance of procedures used solely for the purpose of determining eligibility for research and not when procedures are performed as part of the practice of medicine, the FDA found that no violation of its guidelines occurred.[4] It concluded in part that:

> It appears that selection of antiretroviral therapy was made after giving consideration to Mr. Dimmick's viral load, CD4 count, protease inhibitor resistance genotype; the selection of antiretroviral regimen does not appear to have been made so that Mr. Dimmick would be eligible for research studies. Thus it

---

[4]FDA guidelines provide in pertinent part:

> Procedures that are to be performed as part of the practice of medicine and which would be done whether or not study entry was contemplated, such as for diagnosis or treatment of a disease or medical condition, may be performed and the results subsequently used for determining study eligibility, without first obtaining consent. On the other hand, informed consent must be obtained prior to initiation of any clinical screening procedure that is performed *solely* for the purpose of determining eligibility for research.

Def. Exh. 20; Goebel testimony.

appears that Mr. Dimmick received routine, standard care for treatment of his multiple drug-resistant HIV disease.

*Id*.

As for the BI complaint, Dimmick complained that Dr. Lampiris had improperly enrolled him in the tipranavir study without his written informed consent.[5] BI audited SFVAMC's investigational study site, and the study was allowed to proceed. Dr. Lampiris was never informed of any negative findings.

**G. VHA Handbook**

VA doctors treating patients are required to comply with the guidelines set forth in the Veterans Health Administration ("VHA") Handbook ("handbook"), including those specifying the procedures for obtaining and documenting a patient's informed consent to medical treatment. Pl. Exh. 1. Most of the handbook is devoted to explaining when and under what circumstances written consent is required. However, it also delineates those circumstances requiring only oral consent.

The relevant provisions of the handbook provide in pertinent part:

> **3. SCOPE**
>
> It is VHA policy that VA patients may accept or refuse any treatment offered to them. Except as otherwise provided in this Handbook, diagnostic and therapeutic treatments or procedures must be undertaken only with prior, informed consent of the patient. In order to give informed consent, the patient, or the patient's surrogate decision-maker,. . . must understand the nature of the treatment or procedure to be undertaken, the benefits and risks of the treatment, the alternatives to the proposed course of action, and the expected outcome if the treatment is declined. The practitioner must explain this information in language the patient can understand. The patient must be allowed to ask questions and to make a decision freely without coercion or duress. The consent process is completed by appropriate documentation in the medical record.
>
> **a.** **Discussion of Risks**. Every treatment or procedure, regardless of how minor, involves some risk. As part of good medical practice, the treating practitioner must advise the patient of these risks as well

---

[5]There is no documentary record evidence regarding Dimmick's BI complaint. Nor are the specific dates of the BI complaint or resolution evident from the record. However, Dr. Lampiris testified that sometime after the tipranavir study commenced in Spring 2003, he received a call from BI that a patient had complained and that BI needed to audit Dr. Lampiris' records. *See* Tr. Oct. 19, 2006, at 44-46.

as the benefits of treatment. Signature consent is not required; e.g., to administer most drugs or perform minor procedures; however, the practitioner must document in a progress note that the treatment or procedure and its indications were discussed with the patient.[6]

**b.** **Criteria for Signature Consent.** In addition to the informed consent discussion, the patient's signature consent must be obtained for all diagnostic and therapeutic treatments or procedures that:

(1) Require the use of sedation;

(2) Require anesthesia or narcotic analgesia;

(3) Are considered to produce significant discomfort to the patient;

(4) Have a significant risk of complication or morbidity;

(5) Require injections of any substance into a joint space or body cavity;

(6) Involve testing for HIV; and

(7) Are listed in Appendix A.[7]

. . . .

**6. DOCUMENTATION OF THE INFORMED CONSENT DISCUSSION**

a. **Process.** The informed consent process must be appropriately documented in the medical record.

(1) Signature consent is not required for administration of most drugs or the performance of minor procedures. However, the practitioner must discuss these treatments or procedures with the patient and must document the discussion in a progress note.

---

[6]The court clarified at trial that the "written informed consent" referred to by Dimmick and the testifying doctors was synonymous with the "signature consent," referenced in the handbook. In other words, "written informed consent" does not necessarily mean that the information itself regarding the treatment is in writing. Instead, it means that the patient gives his or her approval in writing, by providing a signature.

[7]Appendix A, which states that it is not exhaustive, lists 35 specific treatments and procedures requiring signature consent. It also provides that the hazardous drug, antabuse, and investigational drugs or procedures require signature consent. Regarding investigational drugs or procedures, the handbook refers the reader to the section entitled "Requirements for the Protection of Human Subjects."

> (2) For treatments and procedures that require the patient's signature consent, documentation must include a progress note that details the consent discussion **and** . . . other VA authorized consent form signed by the patient and the practitioner who obtained the consent.

Paragraph 6(b) of the handbook then describes the requirements of an informed consent progress note. Paragraph 6(b) regarding signature consent, provides that "[t]he signature of the patient on the . . . VA authorized consent form does not eliminate the need for a thorough discussion with the patient to obtain consent before institution of the treatment or procedure. The patient's signature on a VA authorized consent form is required, in addition to documentation of the informed consent discussion in the progress notes."

A routine progress note typically includes post-treatment documentation of the oral discussion between the doctor and the patient of the risks and benefits of the proposed treatment or medication. It should also document the oral, but not written consent of the patient. In comparison, an "informed consent progress note" is utilized under circumstances involving more invasive procedures. *See* Tr. Oct. 16, 2006, at 49-50. It is much more detailed than a routine progress note, and requires separate documentation and a written signature from the patient. Examples of procedures requiring written consent include spinal taps, HIV diagnosis, cancer chemotherapy,[8] and other invasive procedures. Additionally, written consent is also required by the handbook when the patient is a research subject.

Written consent under the handbook is *not* required for the routine treatment of HIV or the prescription of FDA-approved HIV medications. Obtaining oral rather than written consent for prescribing FDA-approved drugs is consistent with Drs. Lampiris' and Higashi's practices. In fact, none of the VA doctors testifying in this case – including Drs. Green, Higashi, Lampiris, or Jensen – testified that they ever obtained written consent for the

[8]The side effects of cancer chemotherapy are more frequently life-threatening than those associated with HIV medications.

prescription of HIV medications prescribed to Dimmick, and all agreed that the November 7, 2002 regimen prescribed by Dr. Lampiris was FDA-approved and routine in the treatment of HIV. Additionally, the potential side effects of FDA-approved HIV drugs, including those prescribed to Dimmick in this case, are not considered to "produce significant discomfort" under the handbook at paragraph 3(b)(3), thereby requiring written consent.

There is also no requirement in the handbook that, in conjunction with routine medical care and the routine prescription of medications, VA doctors discuss with patients why they have not chosen alternative drugs, and document that discussion in the progress note. All of the doctors that testified in this case agree that is important to give patients information regarding potential side effects of medication being prescribed and information about the risks of foregoing treatment. However, it is not Dr. Lampiris' practice, nor that of any doctor who testified at trial, to discuss with a patient the efficacy of drugs that he is *not* recommending. In Dimmick's case, Dr. Lampiris believed that he was recommending the optimal regimen and that, in his opinion, other drugs would have been sub-optimal. Consistent with his normal practice, he did not discuss less effective alternatives with Dimmick.

**H. Alternatives to the November 7, 2002 Drug Regimen**

The essence of Dimmick's negligence claim is that his consent to take the drugs prescribed on November 7, 2002, was not sufficiently informed because he was not told about an alternative drug that may have produced fewer side effects and to which his HIV may have been less resistant. Dimmick relied in large part on an October 2, 2002 genotype report (the "Trugene report") which indicated that Dimmick had a lesser resistance to the drug tenofovir than he did to ddI, the drug prescribed by Dr. Lampiris which Dimmick believes caused his neuropathy. Dimmick asserts that tenofovir was a viable alternative to ddI, and that Dr. Lampiris should have informed him of this alternative.

Dr. Green was not sure whether the Trugene report was in the packet of information

faxed to SFVAMC by Dr. Drum in anticipation of Dimmick's November 7, 2002 visit. However, it was not among the papers received by Drs. Lampiris and Higashi prior to their appointment with Dimmick. Dimmick believed that he may have brought the information with him on November 7, 2002; however, neither Drs. Lampiris nor Higashi received or reviewed the report - either by fax or by personal delivery.

However, in Dr. Lampiris' clinical opinion, even if he had reviewed the Trugene report on November 7, 2002, it would not have altered his opinion regarding the most effective drug regimen for Dimmick. In determining which drugs are likely to be active against a patient's HIV, Dr. Lampiris considers the patient's specific PI and RT mutations. He does not necessarily rely on genotype reports such as Trugene because those reports are computer-generated and do not reflect current interpretations of drug resistance to HIV gene mutations. As he explained, the computer-generated reports are helpful to generalists and practitioners with less expertise in treating HIV/AIDS, but he prefers to review the data upon which the reports are based for himself in order to evaluate the patterns of mutations.

Dr. Lampiris concluded that tenofovir was not an optimal treatment choice for Dimmick because it is less effective for patients with certain mutations, including those reflected in Dimmick's medical records which were reviewed by Drs. Lampiris and Higashi prior to Dimmick's November 7, 2002 visit. *See* Def. Exh. A7. Based on his experience and expertise, Dr. Lampiris did not believe that tenofovir would be effective given Dimmick's specific HIV mutations. Additionally, tenofovir has more serious side effects than ddI. Although rare, it can result in kidney failure requiring hemodialysis. Dr. Higashi reached the same conclusion, and agreed with Dr. Lampiris that tenofovir would not have been as effective as the regimen proposed.

Because Dr. Lampiris was not recommending tenofovir, he did not discuss it with Dimmick. Additionally, because Dimmick did not refuse the recommended treatment, Drs. Lampiris and Higashi did not believe that it was necessary to discuss less effective

alternatives with him.

Dr. Lampiris acknowledged that other doctors may have disagreed with him regarding the efficacy of tenofovir. Specifically, Dr. Lampiris acknowledged that, in the papers faxed to him by Dr. Drum prior to Dimmick's appointment, there was documentation of an email exchange between Dimmick's treating physician, Dr. Green, and another physician, Dr. Holodniy, also an expert in the treatment of HIV/AIDS. The email exchange suggested that Dr. Holodniy believed that tenofovir was a viable option for Dimmick. Dr. Holidniy did not testify at trial, and thus, the basis for his opinion is unknown.

Although Dr. Lampiris had no recollection regarding whether he actually reviewed the email exchange between Drs. Green and Holodniy, he believes that Dr. Holodniy's expertise is no greater than his own and that his medical judgment was warranted by the information available to him at the time it was rendered. Dimmick elected not to present an expert to refute Dr. Lampiris' medical judgment, relying instead on the computer-generated Trugene report.

## ISSUE

The issues before the court are whether the VA doctors were required to obtain Dimmick's informed consent in writing as well as orally and whether they provided him with information sufficient to inform his consent prior to taking two specific prescribed medications, ddI and ritonavir.

## CONCLUSIONS OF LAW

To the extent that any of the following conclusions of law are deemed to be findings of fact, or mixed questions of law and fact, they are incorporated into the Findings of Fact. Similarly, to the extent any of the Findings of Fact are deemed to be Conclusions of Law, they are incorporated into the Conclusions of Law.

### A. Written Consent was not required for the November 7, 2002 Drug Regimen

There is no dispute that Dimmick did not provide written consent regarding the November 7, 2002 drug regimen prescribed by Dr. Lampiris.

**1. Written Consent was not Required under Either California or Federal Law**

California law applies to this case. *Jackson v. United States*, 881 F.2d 707, 711-12 (9th Cir. 1989) (state law governs issues regarding substantive liability in FTCA cases). Liability for negligence under California law requires proof of the following elements: (1) a legal duty of care; (2) a breach of that duty; and (3) causation. *Ann M. v. Pacific Shopping Ctr.*, 6 Cal.4th 666, 673 (Cal. 1993).

A physician in California generally has a duty to obtain a patient's informed consent before performing treatment or an operation. *See Cobbs v. Grant*, 8 Cal.3d 229, 240-41 (Cal. 1972) (finding failure to obtain informed consent constitutes an action for negligence). The scope of a physician's duty to disclose is set by law rather than by the custom of physicians. *Id.* at 243. Nevertheless, a physician is required to provide "such additional information as a skilled practitioner of good standing would provide under similar circumstances." *Id.* at 244-45.

Under California law, this is a duty "of reasonable disclosure of the available choices with respect to proposed therapy and of the dangers inherently and potentially involved." *Arato v. Avedon*, 5 Cal.4th 1172, 1183 (Cal. 1993) (en banc) (quoting *Cobbs*, 8 Cal.3d at 242). "The scope of a physician's duty to disclose is measured by the amount of knowledge a patient needs in order to make an informed choice." *Truman v. Thomas*, 27 Cal.3d 285, 292 (Cal. 1980)

For treatment the physician recommends, the physician must apprise the patient of the material risks inherent in the procedure and the material risks of not undergoing the treatment. *Truman v. Thomas*, 27 Cal. 3d 285, 291 (1980). "Material information is that which the physician knows or should know would be regarded as significant by a reasonable person in the patient's position when deciding to accept or reject the recommended medical procedure." *Id.* It does not include information which is "commonly appreciated." *Id.* Moreover, a "mini-course in medical science is not recommended." *See Mathis v. Morrissey*, 11 Cal.App.4th 332, 339 (Cal. Ct. App. 1992). It is the plaintiff's

burden to prove materiality. *See Mathis*, 11 Cal.App.4th at 346-47.

On the other hand, most California appellate courts have rejected a duty of disclosure for treatment the physician does not recommend. *Parris v. Sands*, 21 Cal.App.4th 187, 193 (Cal. Ct. App. 1993). A physician's failure to recommend a procedure is evaluated under ordinary medical negligence principles. *Vandi v. Permanente Medical Group, Inc.*, 7 Cal.App.4th 1064, 1070 (Cal. Ct. App. 1992).

Additionally, "it is a general rule that a difference of medical opinion concerning the desirability of one particular medical procedure does not, however, establish that the determination to use one of the procedures was negligent." *Mathis*, 11 Cal.App.4th at 342 (citations omitted). Instead,

> [D]ifferent doctors may disagree in good faith upon what would encompass the proper treatment or diagnosis of a medical problem in a given situation. Medicine is not a field of absolutes. There is not ordinarily only one correct route to be followed at any given time. There is always the need for professional judgment as to what course of conduct would be most appropriate with regard to the patient's condition. It is for the doctor to use his best judgment to pick the proper one.

*Id.* (citations omitted).

In addition to warning of potential risks of treatment, under California law, "in order to satisfy his or her duty to the patient and to obtain the patient's informed consent, [a physician must] disclose personal interests unrelated to the patient's health, whether research-related or economic, that may affect his or her medical judgment." Levy et al., 3 California Torts, § 31.14[4A], Lack of Informed Consent (2006) (citing *Moore v. Regents of Univ. of Cal.*, 51 Cal.3d 120, 129, 131-32 (Cal. 1990).

California law typically does not require written consent. *See generally* B.E. Witkin, 3 *Summary of California Law* (10th ed. 2005) §§ 395-416 at 609-32. An exception exists where one is the subject of human experimentation. *See* Cal. Health & Safety Code § 24170 et seq. The California statutes governing human experimentation also incorporate pertinent federal law regarding the protection of human research subjects. *See id.* at § 24178(h) (noting that "[r]esearch conducted pursuant to this section shall adhere to federal

regulations governing informed consent pursuant to Section 46.116 of Title 45 of the Code of Federal Regulations"). Federal law, as incorporated by California statutes, requires written consent only where one is a subject of human experimentation. *See* 45 C.F.R. §§ 46.101 et seq.

On September 26, 2005, in related case number 04-4965 PJH, this court dismissed Dimmick's claim under Cal. Health and Safety Code § 24170, based on a finding that Dimmick was at no time a subject of human experimentation or research by the VA or any of its physicians. The evidence adduced at trial confirmed this conclusion. Because Dimmick was not a subject of medical experimentation or of experimental or innovative treatment, nor was he even an *applicant* for the tipranavir study since he failed to apply for the study once notified, the VA doctors were not required by either California or federal law to obtain his written consent for the medication prescribed on November 7, 2002.

**2. Written Consent was Not Required by the VHA Handbook or FDA Policies**

The court has set forth in some detail above in its findings of fact, the actual language of the handbook and the court's finding that it does not require written consent for routine treatment of HIV and the prescription of FDA-approved HIV medications. The court's factual finding is amply supported by the testimony of all of the doctors who testified on this issue. All who were asked, testified that the prescription of FDA-approved drugs, such as the two at issue here, did not require the patient's written consent, but only that his oral consent be noted in a routine progress note, as was done by Drs. Higashi and Lampiris. The court also finds it significant that Dimmick's own treating physician, whose care Dimmick has not complained about, did not obtain Dimmick's written consent for the prescription of FDA-approved medication during the ten or so years he has treated Dimmick.

Additionally, under FDA guidelines, where drugs or procedures are provided for the *treatment* of a medical condition and not "solely" for the purpose of research written consent is not required.

Accordingly, the court finds that neither the VA nor FDA guidelines required that the VA doctors obtain Dimmicks' written consent on November 7, 2002.

**B. Dimmick's Consent was Sufficiently Informed**

Dimmick's surviving negligence claim also fails because there was no breach of the duty to obtain informed consent, and additionally, for lack of causation.

There is no dispute among the parties or the witnesses in this case that Dimmick was entitled to receive sufficient information to render informed consent. There is also no dispute that Dimmick voluntarily accepted the drug regimen prescribed by Dr. Lampiris on November 7, 2002, and filled his prescriptions and subsequently took the medications.

Instead, Dimmick argues that his consent was not valid because the doctors did not provide him with sufficient information to make an informed decision. Specifically, Dimmick contends that, with respect to ddI, he should have been informed of alternatives with more tolerable side effects, namely tenofovir, a drug to which his HIV was less resistant. Additionally, he contends that he only agreed to take the ddI, with its potential neuropathic side effects, because he thought he had to in order to gain entry into a drug study. As for the ritonavir, Dimmick contends that Dr. Lampiris failed to disclose an interest in the drug - specifically, that he served as a consultant for Abbott Laboratories.

There is no dispute that Dimmick was aware of the potential risks or side effects for both ddI and ritonavir, based on his past use and experience, and his conversations with Drs. Lampiris, Higashi, and Vu on November 7, 2002. Dimmick acknowledged and discussed side effects he had previously experienced and his concerns regarding a potential recurrence of both neuropathy and depression. Additionally, it was clear to both Drs. Lampiris and Higashi that Dimmick was very knowledgeable about HIV treatments not merely from his own extensive experience, but also from the research Dimmick conducted on his own. Accordingly, there were no risks or side effects of which Dimmick was not sufficiently informed.

In terms of the benefits, Dimmick was also well aware of those. He knew that he

had a virulent, highly drug-resistent form of HIV and that he was in bad shape at the time of the November 7, 2002 visit. Dimmick also knew that absent drug therapy, he was at high risk for opportunistic infections, other diseases, and death. In short, Dimmick knew that his HIV mandated immediate treatment with some form of drug therapy.

Weighing the risks of his HIV and the drugs' potential side effects with the benefits of the drug regimen, Dimmick made an informed decision to fill the prescriptions and take the medications.

As for the tenofovir, because Drs. Lampiris and Higashi were not recommending that drug, they had no duty under California law to discuss it with Dimmick. Accordingly, a simple negligence analysis applies to this claim. To prove negligence in not prescribing a particular course of treatment, Dimmick needed to present evidence that undermined the overwhelming expert testimony that convincingly proved that Drs. Lampiris and Higashi provided the requisite degree of care in this case. Dimmick chose, however, not to put on expert testimony, but instead to rely on the Trugene study and the testimony of Dr. Green, and the evidence documenting the email exchange between Drs. Green and Holodniy.

However, the computer-generated Trugene study pales in comparison to the persuasive expert testimony to the contrary. Moreover, to the extent that Dr. Green's testimony could be construed to reflect disagreement with Dr. Lampiris' medical judgment, the court accords Dr. Lampiris' judgment and testimony thereon greater weight because Dr. Green has less expertise in the field, and has even himself prescribed for Dimmick the very drugs prescribed by Dr. Lampiris – ddI and ritonavir. Moreover, Dr. Holodniy did not testify at all; thus, there is no evidence explaining his alleged opinion, suggested in the email, as to why he may have believed that tenofovir was a more viable option. In any event, even if there had been such testimony from Dr. Holodniy, that still would not have been enough. At a minimum, Dimmick needed to present concrete evidence to this court that weighed against Drs. Lampiris' and Higashi's judgment.

Because there was no legal obligation for Drs. Lampiris and Higashi to raise and

discuss medications with Dimmick that they did not recommend, there was no breach of a legal duty owed to Dimmick.

Additionally, as for Dimmick's belief that he was required to take the ddI to enter a drug study, this belief was unreasonable. Both Drs. Lampiris and Higashi, and subsequently, Dr. Jensen, all testified that only a stabilizing regimen - not any particular regimen- was required for potential eligibility for future drug studies. Moreover, none of the doctors promised Dimmick that he would be permitted into a drug trial, and there were no drug trials underway at the time of Dimmick's visits.

Turning to Dimmick's argument that Dr. Lampiris should have informed him of his role as a consultant with respect to the ritonavir, the law is somewhat unclear regarding the scope of Dr. Lampiris' duty to disclose. The only case cited by Dimmick in support of such a duty is factually distinguishable from the circumstances here. The physician in *Moore* developed a cell line from the plaintiff patient's white blood cells and applied for a patent on that cell line, without disclosing that information to the patient. 51 Cal.3d at 127. The California Supreme Court held that the patient stated a claim for lack of informed consent against the physician for using the patient's cells in potentially lucrative medical research without his permission because the physician failed to disclose preexisting research and economic interests in the cells before obtaining consent to the medical procedures by which the cells were extracted. *Id.* The *Moore* court held that "a physician must disclose personal interests unrelated to the patient's health, whether research or economic, that *may affect* the physician's professional judgment." *Id.* at 129.

*Moore* does not necessarily mandate disclosure in this case. Unlike the physician in *Moore*, Dr. Lampiris was not participating in research involving ritonavir, nor did he derive any financial benefit by including ritonavir in Dimmick's drug regimen. Rather, Dr. Lampiris received fixed compensation for his consultant work, unlike the physician in *Moore* who received compensation in exchange for administering treatment. Finally, Dr. Lampiris' testimony that, in prescribing ritonavir as a component of Dimmick's regimen, his

professional judgment was unaffected by his role as a consultant for Abbott went unrebutted.

For all of these reasons, Dimmick has not shown the breach of a duty. Nevertheless, even if the court were to find that Dr. Lampiris had a duty to disclose his role as an Abbott consultant, Dimmick's claim fails for a lack of causation.

Under California law, to succeed on a negligence claim based on lack of informed consent, "[t]here must be a causal relationship between the physician's failure to inform and the injury to the plaintiff." Levy et al., 3 California Torts, § 31.14[4A], Lack of Informed Consent (2006). The plaintiff is required to "show that a prudent person in the plaintiff's position would not have agreed to the procedure if he or she had been properly informed." *Daum v. Spinecare Med. Group, Inc.*, 52 Cal.App.4th 1285, 1311 (Cal. Ct. App. 1997) (citing *Cobbs*, 8 Cal.3d at 245). A patient's subjective, retrospective view is not determinative, though. *Id.* Instead, the test is an objective one, based on a prudent person. *Id.*

Dimmick argues that he would not have taken the ddI had he known that another drug - specifically, tenofovir – was available. As discussed, there was no expert testimony to contradict Dr. Lampiris' professional judgment regarding the particular drug regimen employed in this case, or to contradict Dr. Lampiris' expert opinion that, given Dimmick's mutations and drug-resistance, ddI was superior to tenofovir. Given the absence of evidence on this issue, and the overwhelming evidence that ddI was optimal and that Dimmick's life depended on HIV treatment, Dimmick is unable to demonstrate that a prudent person in his situation would have acted otherwise. Thus, he cannot demonstrate causation.

Evidence of causation with respect to the ritonavir is likewise missing. Dimmick never testified, nor was there any evidence or even a suggestion, that had Dr. Lampiris disclosed his role as a consultant for Abbott, Dimmick would not have taken the ritonavir. Moreover, given Dr. Lampiris' unrebutted testimony regarding the efficacy of ritonavir as a

"booster" for other drugs in Dimmick's regimen and its important role in the regimen, Dimmick has not shown that a prudent person would not have taken the ritonavir in light of Dr. Lampiris' role as a consultant for Abbott.

Accordingly, while the court is sympathetic to Dimmick's long and difficult struggle trying to manage his serious medical condition, the record does not support his claim of negligence. His written consent was not required; he was provided sufficient information about ddI and ritanovir to inform his consent to take them; there was no legal requirement that he be told about tenofovir; he was not told that he would be enrolled in a drug study if he took the ddI and ritanovir; he did not even apply for enrollment in the tipranavir study; it would not have been objectively reasonable for him to have refused to take the prescribed drugs; and even he did not claim that he would not have taken the ritanovir had he known about Dr. Lampiris' consulting position with Abbott.

In view of these findings, it is unnecessary for the court to reach the issue of damages.

**CONCLUSION**

For the above reasons, the court finds in favor of the defendant and against the plaintiff. Final judgment shall be entered for the United States.

Dated: December 15, 2006

**IT IS SO ORDERED.**

PHYLLIS J. HAMILTON
United States District Judge